UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

LAFAYETTE DIVISION

JEANNINE BERTRAND, ET AL	*	**CIVIL NO. 12-0853**
VERSUS	*	**JUDGE DOHERTY**
ELI LILLY & CO.	*	**MAGISTRATE JUDGE HILL**

REPORT AND RECOMMENDATION

Pending before the Court is the Motion to Dismiss Pursuant to Federal Rule of Civil Procedure 12(b)(6) filed by defendant, Eli Lilly & Co. ("Eli Lilly"), on October 11, 2012. [rec. doc. 31]. Plaintiffs, Jeannine Antoinette Thibodaux Bertrand and Alex Bertrand, individually and as the administrator of the estate of his minor child, Aimeé Katherine Bertrand ("Bertrand"), filed opposition on November 1, 2012. [rec. doc. 39]. Eli Lilly filed a Reply Memorandum on November 9, 2012. [rec. doc. 42]. Oral argument was held, after which I took the matter under advisement.

For the following reasons, I recommend that the motion be **GRANTED IN PART AND DENIED IN PART**.

Background

This is a products liability suit which alleges that Jeannine Bertrand's use of the the antidepressant drug, Prozac, during her pregnancy caused birth defects in her third child, Aimeée Katherine Bertrand. On April 10, 2012, the action was filed in this Court

on the basis of diversity jurisdiction pursuant to 28 U.S.C. § 1332, and supplemental jurisdiction over the Louisiana state law claims pursuant to 28 U.S.C. §1367.

In the original complaint, Bertrand asserted negligence and products liability claims against Eli Lilly and its insurer. [rec. doc. 1, ¶ 9]. On June 7, 2012, Eli Lilly filed a Motion to Dismiss Pursuant to Federal Rule of Civil Procedure 12(b)(6) seeking dismissal of plaintiffs' claims of strict products liability, common law negligence, inadequate or negligent testing, negligent promotion, marketing selling, and continued production and sale, as being outside of the scope of the Louisiana Products Liability Act ("LPLA"), LA. REV. STAT. 9:2800.51 *et seq*. [rec. doc. 8]. On August 3, 2012, Bertrand filed a Motion for Leave to File First Amending and Supplemental Complaint, seeking to delete the common law negligence claims pled in the original complaint. [rec. doc. 25].

Oral argument on the Motion to Dismiss [rec. doc. 8] and the Motion for Leave [rec. doc. 25] was held on September 27, 2012, at which time the Court denied the Motion to Dismiss as premature, reserving movant's right to re-urge the motion at a later time. The Court further granted the Motion for Leave, and allowed the First Amending and Supplemental Complaint to be filed. [rec. doc. 29].

On October 11, 2012, Eli Lilly filed the instant Motion to Dismiss Pursuant to Federal Rule of Civil Procedure 12(b)(6). [rec. doc. 31]. By this Motion, Eli Lilly seeks to dismiss Bertrand's First Amending and Supplemental Complaint on the grounds that it

fails to allege enough facts to give defendant fair notice of the basis of the claims against it. Specifically, it argues that the amending complaint is "nothing more than a formalistic recitation of labels and conclusions, which are devoid of factual enhancement and which fail to allege essential elements of any claim" under the LPLA, in derogation of the pleading requirements set forth in *Ashcroft v. Iqbal,* 556 U.S. 662, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).

Motion to Dismiss Standard

When deciding a Rule 12(b)(6) motion to dismiss, "[t]he court accepts all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff." *In re Katrina Canal Breaches Litig*., 495 F.3d 191, 205 (5th Cir. 2007) (*quoting Martin K. Eby Constr. Co. v. Dallas Area Rapid Transit*, 369 F.3d 464, 467 (5th Cir. 2004)). To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Id*. (*quoting Twombly*, 127 S.Ct. at 1974). However, the court is not bound to accept legal conclusions framed as factual allegations. *Iqbal*, 129 S.Ct. at 1950.

"Factual allegations must be enough to raise a right to relief above the speculative level[.]" *In re Katrina*, 495 F.3d at 205 (*quoting Twombly*, 127 S.Ct. at 1965). Thus, "a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will

not do[.]" *Twombly*, 127 S.Ct. at 1964-65 (citations, quotation marks, and brackets omitted); *see also Iqbal*, 129 S.Ct. at 1950. The court does not accept as true "conclusory allegations, unwarranted factual inferences, or legal conclusions." *In re Great Lakes Dredge & Dock Co. LLC*, 624 F.3d 201, 210 (5th Cir. 2010) (*quoting Ferrer v. Chevron Corp*., 484 F.3d 776, 780 (5th Cir. 2007)).

Within days after *Twombly* was decided, the Supreme Court, citing *Twombly*, said in *Erickson v. Pardus*, 551 U.S. 89, 93, 127 S.Ct. 2197, 2200 (2007):

> Federal Rule of Civil Procedure 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." Specific facts are not necessary; the statement need only " 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.' "

Id. (*citing Twombly*, 550 U.S. at 555).

In *Lormand v. US Unwired, Inc*., 565 F.3d 228 (5th Cir. 2009), the Fifth Circuit explained *Twombly's* "plausibility" standard of pleading applicable to Rule 8(a)(2) as follows:

> The complaint (1) on its face (2) must contain enough factual matter (taken as true) (3) to raise a reasonable hope or expectation (4) that discovery will reveal relevant evidence of each element of a claim. "Asking for [such] plausible grounds to infer [the element of a claim] does not impose a probability requirement at the pleading stage; it simply calls for enough facts to raise a *reasonable expectation that discovery will reveal* [that the elements of the claim existed]." (emphasis added)

Id. at 257 (*quoting Twombly*, 127 S.Ct. at 1965).

The decisions in *Twombly* and *Iqbal* have not changed the pleading requirements under Rule 8 of the Federal Rules of Civil Procedure, but rather merely "explicate[]" the Rule. *See Diamond Services Corp. v. Oceanografia, S.A. De C.V.*, 2011 WL 938785, *2 (W.D. La. 2/9/2011), *adopted*, 2011 WL 917825 (W.D. La. 3/15/2011) (*quoting Lormand* 565 F.3d at 258 n.29). *Twombly* itself recognizes that pleading requirements can only be changed by amendment of the Federal Rules. *Lormand*, 565 F.3d at 258 n.29 (*citing Twombly*, 550 U.S. at 569, 127 S.Ct. at 1973 n.14).

As Judge Hanna explained in *Barber v. Bistol-Myers Squibb*, Docket No. 09-1562 (W.D. La. March 31, 2010) [rec. doc. 54], which analysis has been cited approvingly by the undersigned:[1]

> Therefore, while the court is not to give the "assumption of truth" to conclusions, factual allegations remain so entitled. Once those factual allegations are identified, drawing on the court's judicial experience and common sense, the analysis is whether those facts, which need not be detailed or specific, allow "the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft*, 129 S.Ct. at 1949, *Twombly*, 555 U.S. at 556, 127 S.Ct. at 1965. This analysis is not substantively different from that set forth in *Lormand*, *supra*, nor does this jurisprudence foreclose the option that discovery must be undertaken in order to raise relevant information to support an element of the claim. The standard, under the specific language of Fed. Rule Civ. P. 8(a)(2), remains that the defendant be given adequate notice of the claim and the grounds upon which it is based. This standard is met by the "reasonable inference" the court must make that, with or without discovery, the facts set forth a plausible claim for relief under a particular theory of law provided there is a "reasonable expectation" that "discovery will reveal relevant evidence of

[1] *Diamond Services Corp.,* 2011 WL 938785 at *2.

> each element of the claim." *Lormand*, 565 F.3d at 257, *Twombly*, 555 U.S. at 556, 127 S.Ct. at 1965.

Id. at 5–9.

Subsequent to *Barber*, the Fifth Circuit described the *Iqbal/Twombly* analysis as follows:

> To avoid dismissal, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009) (*quoting Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). To be plausible, the complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555, 127 S.Ct. 1955. In deciding whether the complaint states a valid claim for relief, we accept all well-pleaded facts as true and construe the complaint in the light most favorable to the plaintiff. *MySpace*, 528 F.3d at 418[2] (*citing Hughes*, 278 F.3d at 420). We do not accept as true "conclusory allegations, unwarranted factual inferences, or legal conclusions." *Ferrer v. Chevron Corp*., 484 F.3d 776, 780 (5th Cir.2007) (*quoting Plotkin v. IP Axess Inc*., 407 F.3d 690, 696 (5th Cir.2005)); *see also Iqbal*, 129 S.Ct. at 1940 ("While legal conclusions can provide the complaint's framework, they must be supported by factual allegations.").

In re Great Lakes Dredge & Dock Co. LLC, 624 F.3d 201, 210 (5th Cir. 2010).

More recently, the Fifth Circuit reiterated *Iqbal* and *Twombly's* plausibility standard in *Harold H. Huggins Realty, Inc. v. FNC, Inc*., 634 F.3d 787 (5th Cir. 2011) as follows:

> "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 129 S.Ct. at 1949 (*quoting Twombly*, 550 U.S. at 570). A

[2] *Doe v. Myspace*, 528 F.3d 413, 418 (5th Cir. 2008).

> claim for relief is plausible on its face "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. A claim for relief is implausible on its face when "the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct."

Id. at 796.

With this standard and analytical framework in mind, the undersigned now goes to plaintiffs' complaint and amending complaint to see if they meet these pleading requirements.

Law and Analysis

In the original complaint, plaintiffs allege that Jeannine Bertrand, married to Alex Bertrand, was prescribed the antidepressant drug, Prozac, beginning in November, 1996. [rec. doc. 1, ¶ 6]. She remained on her daily regime of Prozac through May, 1997, when her third child, Aimeé ("Aimeé") Katherine Bertrand, was conceived. When Aimeé was approximately six to eight months old, she was diagnosed with spina bifida occulta, sprengles deformity, fused and missing ribs on the left side, congenital scoliosis, tethered spinal cord, hip displasia, thoracic insufficiency syndrome, an extra right rib, and a misplaced and misshaped right kidney. [rec. doc. 1, ¶ 7]. Since her diagnoses, Aimeé has undergone the placement of vertical expandable prosthetic titanium ribs. [rec. doc. 1, ¶ 8].

In the First Amending and Supplemental Complaint, plaintiffs allege that Aimeé's birth defects and related damages are "the direct and proximate result of breaches of

obligations owed by defendants to plaintiffs, including defects in design, marketing, manufacture, distribution, instructions and warning by the defendants." [rec. doc. 30, ¶ 9].

These alleged defects and breaches include:

A. Failure to instruct and/or warn women attempting to conceive of the potential birth defects associated with Prozac;

B. Manufacturing, producing, promoting, formulating, creating and/or designing Prozac without adequately testing it;

C. Failing to provide adequate warning of the dangers associated with Prozac;

D. The defects in designing, formulating, researching, developing, manufacturing, marketing, promoting and selling a medication when it knew or reasonably should have known of the propensity to cause birth defects;

E. Its strict liability under the Louisiana Products Liability Act as a result of its design, development, manufacture, marketing and sale of a medication which is defective and unreasonably dangerous to women attempting to conceive and pregnant women;

F. The continued production and sale of this medication given the propensity of this medication to cause birth defects;

G. Providing inaccurate labeling and inadequate warnings and instructions;

H. Utilizing testing methods which are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented;

I. Other breaches and defects which may be shown through discovery or at trial; and

J. Generally, the failure of these defendants to act with the required degree of care commensurate with the existing situation.

[rec. doc. 30, ¶ 9].

The LPLA establishes the "exclusive theories of liability for manufacturers for damage caused by their products." LA. REV. STAT. § 9:2800.52. In the context of pharmaceutical drugs, the Fifth Circuit outlined the parameters of a claim under the LPLA as follows: a plaintiff must show that: (1) that the defendant is a manufacturer of the product; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that this characteristic made the product "unreasonably dangerous"; and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else. *Stahl v. Novartis Pharmaceuticals Corp*., 283 F.3d 254, 261 (5th Cir. 2002) (*citing* LA. REV. STAT.§ 9:2800.54(A).

Here, plaintiffs allege that Eli Lilly manufactured the antidepressant drug, Prozac, which Jeannine Bertrand was taking as prescribed at the time she became pregnant. The complaint further alleges when the child was approximately six to eight months old, she was diagnosed with serious conditions, including spina bifida occulta, rib and kidney deformities, congenital scoliosis, tethered spinal cord, hip displasia, and thoracic insufficiency syndrome.

Additionally, plaintiffs assert that since her diagnoses, the child has undergone the placement of vertical expandable prosthetic titanium ribs. Plaintiffs allege that these birth defects and related damages are "the direct and proximate result of breaches of

obligations owed by defendants to plaintiffs, including defects in design, marketing, manufacture, distribution, instructions and warning by the defendants." With these allegations, I find that plaintiffs have pled enough facts to draw a reasonable inference that they have a plausible claim for relief under the LPLA.

Regarding the specifics of Bertrand's claims, Eli Lilly first argues that the non-failure-to-warn claims contained in ¶¶ 9B, 9D, 9E, 9F, 9H, 9I, and 9J are insufficiently pled. These claims are for manufacturing, producing, promoting, formulating, creating and/or designing Prozac without adequately testing it; defects in designing, formulating, researching, developing, manufacturing, marketing, promoting and selling a medication when it knew or reasonably should have known of the propensity to cause birth defects; strict liability as a result of its design, development, manufacture, marketing and sale of a medication which is defective and unreasonably dangerous to women attempting to conceive and pregnant women; continued production and sale of this medication given the propensity of this medication to cause birth defects; utilizing testing methods which are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods which have not been properly established and documented; other breaches and defects which may be shown through discovery or at trial, and the failure of these defendants to act with the required degree of care commensurate with the existing situation. In essence, defendant argues, these are claims for construction or composition defect or design defect under the LPLA.

A product is "unreasonably dangerous" under the LPLA if the product meets at least one of the following criteria: (1) the product is unreasonably dangerous in construction or composition; (2) the product is unreasonably dangerous in design; (3) the product is unreasonably dangerous because an adequate warning about the product has not been provided, or (4) the product is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product. *Stahl*, 283 F.3d at 261 (*citing* LA. REV. STAT. §§ 9:2800.55-58).

To establish a construction or composition defect claim, a plaintiff must establish that, at the time the product left its manufacturer's control, the product "deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." LA. REV. STAT. § 9:2800.55.

A product is unreasonably dangerous in design if at the time the product left the manufacturer's control: (1) there existed an alternative design for the product that was capable of preventing the plaintiff's damage, and (2) the likelihood that the product's design would cause the plaintiff's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting the alternative design and the adverse effect if any of the alternative design on the utility of the product. *Guidry v. Adventis Pharmaceuticals, Inc*., 418 F.Supp.2d 835, 840 (M.D. La. 2006) (citing LA. REV. STAT. § 9:2800.56).

In a similar case, *Winslow v. W.L. Gore & Assoc., Inc*., 2011 WL 866184 (W.D. La. 2011), Judge Kirk addressed defendant's argument that plaintiff's claims under the LPLA for defect in design were insufficiently pled under *Twombly* and *Iqbal*. There, plaintiff alleged that a mesh medical device implanted during hernia surgery had deteriorated, resulting in damages and injuries including infection and the necessity for a second surgery. In finding that plaintiffs had adequately set forth facts regarding a products claim, Judge Kirk noted that neither *Twombly* nor *Iqbal* were products liability suits. He further observed that:

> [T]his is a products liability case where almost all of the evidence is in the possession of defendant or other entities. Proof will necessarily be technical in nature and it is likely impossible for plaintiff to state more specific allegations regarding defects in manufacture and design without first having the benefit of discovery and of expert analysis, neither of which is required in order to file suit.

Id. at * 2.

The undersigned agrees with Judge Kirk's analysis. As I indicated to the parties at oral argument, the evidence necessary to prove plaintiff's case is likely within the sole knowledge of defendants. Without having the ability to conduct discovery, it would be nearly impossible for plaintiffs to obtain that information. The Supreme Court made clear that the standard set forth in *Twombly* "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary claims or elements." *Winslow* at *3 (*quoting Twombly*, 550 U.S. at 556). As Judge Kirk stated, "[i]t is not unreasonable to assume that discovery will uncover evidence which tends to prove a

defect in the manufacture and design" which in turn led to the damages alleged. *Id*. Thus, the undersigned finds that, based on the allegations in the pleadings, discovery could be reasonably expected to reveal relevant information as to plaintiffs' claims for construction or composition defect or design defect under the LPLA in this case.

In its Reply brief, Eli Lilly argues that *Winslow* is distinguishable because it involved a claim against a medical device manufacturer, not a pharmaceutical manufacturer. [rec. doc. 42, p. 2]. However, Judge Trimble recently addressed the sufficiency of allegations of a design defect under the LPLA against a pharmaceutical manufacturer in *Harris v. Merck & Co., Inc.*, 2012 WL 5384720 (W.D. La. Nov. 1, 2012). There, plaintiff filed a claim under the LPLA alleging that she sustained damages as a result of taking Zocor, and that said drug was defective, dangerous, unfit and unsuitable to be marked and sold in commerce, and lacked proper warnings as to the danger associated with its use.

Merck moved to dismiss plaintiff's LPLA design defect claim on the same grounds asserted in this case, namely, that plaintiff had not alleged the existence of an alternative design which would have prevented plaintiff's alleged damages. *Id*. at *3. Judge Trimble found that plaintiff's factual allegations in the complaint were sufficient under Rule 8(a) to apprise Merck of the crux of plaintiff's LPLA claim, in that the complaint alleged a defect in the dosage design and asserted that a lower dose design would have prevented plaintiff's injuries. Here, I find that the allegations in ¶¶ 9B, 9D, 9E, 9F and 9H of the

amending complaint, that is, that the medication was defective and unreasonably dangerous to women attempting to conceive and pregnant women because it caused birth defects, were adequately pled to place Eli Lilly on notice the claims against it for design defect under the LPLA.

Eli Lilly further argues in its Reply that plaintiffs' LPLA construction or composition claim must fail because they do not allege that the Prozac allegedly prescribed to Jeannine Bertrand deviated from defendant's specifications or performance standards. [rec. doc. 42, pp. 3-4]. In *Brennon v. Pfizer Inc*., 2009 WL 2525180 (W.D. La. Aug. 17, 2009) (Hayes, J.), plaintiff, who alleged that she suffered seizures as a result of taking Chantix, filed claims under the LPLA on the grounds that the drug was unreasonably dangerous in construction or composition, in design, because an adequate warning was not provided, and because the drug did not conform to the manufacturer's express warranty. Pfizer moved to dismiss on the ground that the petition failed to set forth a direct claim under the LPLA. Judge Hayes found that the petition "fleshe[d] out" these allegations "by stating that the label contained no warning and/or an inadequate warning for risk of seizures, serious injury, and/or death[,] . . . that Chantix was unreasonably dangerous as designed, because it failed to perform safely when used as intended by ordinary customers in a reasonably foreseeable manner because the risks of seizures, serious injury, and/or death posed by the drug exceeded any benefit that the drug was designed to bestow, and there existed safer alternative methods and designs for the

product [,] . . . that defendant breached express warranties by representing that the product was safe and that it did not produce any unknown dangerous side effects[,] and that plaintiff suffered personal injuries and damage due to defendant's defective design of Chantix, and that, had there been adequate warnings and instructions, [plaintiff] would not have taken Chantix, and would not have been at risk of seizure."

Based on these allegations, Judge Hayes found that plaintiff had alleged and factually supported characteristics of Chantix which might prove to be unreasonably dangerous under the LPLA. She further found that plaintiff's products liability allegations "surpass[ed] mere speculation and 'raise a reasonable expectation that discovery will reveal evidence of' the necessary claims or elements." *Id*. at *4 (*citing In re Southern Scrap Material Co., LLC*, 541 F.3d 584, 587 (5th Cir. 2008)). Applying the reasoning in *Brennon*, I find that plaintiffs have sufficiently pled a claim for construction or composition defect.

At oral argument, counsel for the defendant candidly admitted that, in his view, the *only way* that the pleading requirements of *Iqbal* and *Twombly* could be met in a pharmaceutical case brought under the LPLA was if the plaintiff pled with specificity the precise way in which the design or composition was deficient. Counsel went on to argue that the *only way* that could be done in a pharmaceutical case was for the plaintiff to cite specific medical/scientific tests which showed the defect.

In other words, defendant argues that the plaintiff must come forward with a summary judgment type evidence at the initial pleading stage. The practical effect of such a requirement would be to essentially preclude pharmaceutical cases under the LPLA in federal court because of *Iqbal* and *Twombly*. Neither *Iqbal, Twombly* nor Rule 8 require such specificity at the initial pleading stage. In fact, *Iqbal*, *Twombly* and *Lormand* make it clear that a much less strict standard, that of mere plausibility, is all that is required at the pleading stage. Rule 8 allows for no more strict standard in a pharmaceutical case than in any other case.

Lormand instructs that the court is to perform its analysis to determine the sufficiency of the pleadings by considering the factual allegations (taken as true) based on the Court's experience and common sense. The Court has done just that here. The pleadings allege that Jennine Bertrand, while trying to conceive and pregnant with Aimee', was prescribed Prozac, which she took as prescribed. Aimee' was born with serious birth defects. These are all factual allegations, entitled to the assumption of truth at this stage of the case. The complaint then alleges that the birth defects were caused by Prozac, which were unreasonably dangerous for pregnant women, or women seeking to conceive, to ingest.

The complaint alleges that Prozac was unreasonably dangerous in design and that the defendant failed to sufficiently test Prozac, or that the test results known to the

defendant were not disclosed. These are factual allegations also entitled to the assumption of truth at this stage of the case.

Finally, the complaint alleges that the labeling and warnings were inadequate, in that there was no adequate warning regarding pregnant women (or women seeking to conceive) of the danger to these women in taking Prozac. These are also allegations of fact, entitled to the assumption of truth at this stage. It is true, as argued by the defendant, that the learned intermediary defense applies in Louisiana; the manufacturer's duty to warn is discharged by adequate warning to the learned intermediary, here, the prescribing physician. Counsel for the plaintiff is aware of the effect of the learned intermediary defense in this case.

Again, the court is required to review these allegations based on the court's experience and common sense. The Court construes the allegations regarding inadequate warnings to be allegations that inadequate warnings were provided to the prescribing physicians by the defendants, which caused the prescribing physicians to prescribe Prozac to Jeannine Bertrand because they were not warned, adequately, of the danger to women like Bertrand.[3]

Would more specific allegations be helpful to the defendant? Of course. Would more specific allegations make this analysis easier? Of course. However, that is not

[3] A contrary construction would not require dismissal, and would simply require the plaintiff to amend his complaint to specify that the warning was inadequate as to the learned intermediary. Under the circumstances of this case, that is a waste of time and expense since all parties understand and recognize the existence of the learned intermediary defense.

required. In all likelihood, the specific information which the plaintiff would need to make these more specific allegations are in the sole possession of the defendant. To require that information be more specifically pled at this stage would likely make a pharmaceutical product liability cases essentially impossible to bring in federal court. Clearly, that was not the intent of *Iqbal* or *Twombly*, neither of which were product liability cases, much less pharmaceutical cases.

The sufficiency of the allegations must be viewed by the court using its judicial experience and common sense. I reviewed these allegations with the experience of thirty-six years as a trial lawyer, over twelve years of which have been on this Bench. The factual allegations of the complaint, taken as true, allows the reasonable inference that the defendant is liable for the misconduct alleged. Nothing more is required.

Next, Eli Lilly argues that Bertrand's inadequate warning claims are deficient under the pleading standards of Rule 8(a) and the learned intermediary doctrine. Louisiana applies the "learned intermediary doctrine" to products liability claims involving prescription drugs. *Stahl*, 283 F.3d at 265. Under this doctrine, a drug manufacturer discharges its duty to consumers by reasonably informing prescribing physicians of the dangers of harm from a drug. *Id.*; *Jackson v. Johnson & Johnson*, 2012 WL 2428262 (W.D. La. June 25, 2012) (Hornsby, J.).

The Fifth Circuit has acknowledged that there is a two-prong test governing inadequate-warning claims under the LPLA when the learned intermediary doctrine is

applicable. First, the plaintiff must show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician. *Id*. Second, the plaintiff must show that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury. *Id*.

Eli Lilly argues that Bertrand's claim in ¶ 9A, "failure to instruct and/or warn women attempting to conceive of the potential birth defects associated with Prozac," must be dismissed because "there is no LPLA claim for failure to warn the users of drugs since the learned intermediary doctrine applies." [rec. doc. 31, p. 8]. As to Bertrand's claims in ¶¶ 9C (failing to provide adequate warning of the dangers associated with Prozac) and 9G (providing inaccurate labeling and inadequate warnings and instructions), Eli Lilly argues that they must be dismissed because plaintiffs fail to allege the essential element of a failure-to-warn product liability claim against the manufacturer, namely, that Eli Lilly's failure to warn Jeannine Bertrand's *prescribing physician* of the alleged unreasonably dangerous characteristic of Prozac was both a cause-in-fact and the proximate cause of her child's birth defects. (emphasis in original).

In *Harris, supra*, Merck filed a motion to dismiss plaintiff's failure to warn claim, particularly in light of the learned intermediary doctrine. Merck argued that plaintiff's allegation – that had Merck rendered an adequate warning concerning Zocor prescribers would not have prescribed it to patients such as plaintiff, and would have either switched

to safer products or totally refrained from using Zocor – was inadequate under the learned intermediary doctrine. Judge Trimble found that, while barely sufficient, plaintiff's allegations met the most minimal threshold of the doctrine.

As to Merck's next argument, that plaintiff's failure to allege what warning would have been adequate rendered the claim insufficient, Judge Trimble noted that Merck had cited no authority where dismissal was deemed appropriate on that basis. In conclusion, Judge Trimble opined: "[w]e think this type of argument is more suited for post-discovery motion practice or, possibly, trial, but should not be required at the pleading stage." *Id*. at *4.

In this case, plaintiffs have adequately stated their claim for failure to warn. As stated by the Supreme Court in *Erickson*, Rule 8(a)(2) requires only that the statement of the claim "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." 551 U.S. at 93, 127 S.Ct. at 2200. Here, plaintiffs allege that their child was injured by Jeannine Bertrand's taking Prozac during pregnancy, that Eli Lilly failed to provide warnings of the propensity of this medication to case birth defects, and that Eli Lilly failed to instruct and/or warn women (presumably through their physicians) of attempting to conceive because of the potential birth defects associated with Prozac.

These allegations notified Eli Lilly of the grounds on which the failure to warn claim is based. Further, there is a reasonable expectation that discovery will reveal evidence concerning the applicability of the learned intermediary doctrine, alternative

product design, and other evidence of the necessary claims or elements. *See Nelson v. Mylan Pharmaceuticals, Inc*., 2010 WL 3339274, *5 (W.D. La. Aug. 3, 2010) (Hanna, J.); *Brennon*, *supra*, at *5. Thus, I find that the allegations are sufficient to support a failure-to-warn claim at this stage of the litigation.

However, the boilerplate/catchall allegations of fault plead in paragraphs 9I and 9J of the First Amending Complaint [rec. doc. 30], do not meet the pleading standards of *Iqbal* and *Twombly*. There are no specific factual allegations made in either of these two paragraphs and therefore the Motion to Dismiss should be granted as to paragraphs 9I and 9J of the First Amending Complaint.

CONCLUSION

For those reasons set out above, I recommend that the Motion to Dismiss [rec. doc. 31] be **GRANTED** as to paragraphs 9I and 9 J of the First Amending Complaint and that it be otherwise **DENIED** .

Under the provisions of 28 U.S.C. § 636(b)(1)(C) and Fed.R.Civ.Proc. 72(b), parties aggrieved by this recommendation have fourteen (14) days from service of this report and recommendation to file specific, written objections with the clerk of court. A party may respond to another party's objections within fourteen (14) days after being served with a copy thereof.

FAILURE TO FILE WRITTEN OBJECTIONS TO THE PROPOSED FACTUAL FINDING AND/OR THE PROPOSED LEGAL CONCLUSIONS

REFLECTED IN THIS REPORT AND RECOMMENDATION WITHIN FOURTEEN (14) DAYS FOLLOWING THE DATE OF ITS SERVICE, OR WITHIN THE TIME FRAME AUTHORIZED BY FED.R.CIV.P. 6(B), SHALL BAR AN AGGRIEVED PARTY FROM ATTACKING EITHER THE FACTUAL FINDINGS OR THE LEGAL CONCLUSIONS ACCEPTED BY THE DISTRICT COURT, EXCEPT UPON GROUNDS OF PLAIN ERROR. SEE *DOUGLAS V. UNITED SERVICES AUTOMOBILE ASSOCIATION,* 79 F.3D 1415 (5TH CIR. 1996).

Counsel are directed to furnish a courtesy copy of any objections or responses to the District Judge at the time of filing.

Signed March 13, 2013, at Lafayette, Louisiana.

C. MICHAEL HILL
UNITED STATES MAGISTRATE JUDGE

Copy sent: RFD, CG
On: 3/13/2013
By: MBD